BFGoodrich

8EHQ-0494-12994

The BFGoodrich Company
3925 Embassy Parkway
Akron, Ohio 44333-1799

Contains No CBI

Carl A. Mattia
Vice President
Environmental Health and
Public Management Systems

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ORIGINAL

April 15, 1994

RECD
OFFICE OF POLLUTION
PREVENTION AND TOXICS
94 APR 19 PM 12:57

Document Control Officer
Chemical Information Division
Office of Toxic Substances
Room E-108
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Re: Notice of Substantial Risk Under TSCA Section 8(e)

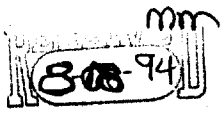
Dear Sir/Madam:

The B.F.Goodrich Company (BFG) submits this notice in accordance with Section 8(e) of the Toxic Substances Control Act (TSCA) and EPA's numerous interpretive statements.

We are advising the EPA of possible evidence of neurotoxicity in an acute toxicity in rats in a pre-TSCA/pre-GLP study dated November 1, 1972. Although we are making this submission to ensure compliance with the latest expressed indications of the EPA for reporting such information, BFG believes that these test results do not demonstrate a human risk.

Background

Cure-rite® 20 was evaluated as a rubber accelerator but is not manufactured or marketed. In the process of reviewing old documents, BFG has identified and reviewed a pre-TSCA/pre-GLP acute toxicity study in rats. The report notes neurotoxic signs following the forced feeding of high doses to rats. However, the detail of the report is not sufficient to enable a determination of the incidence of these observations or whether they occurred in moribund or non-moribund animals.



17 pgs.

Significance/Assessment of the Data

Although the limited reporting of this pre-GLP/pre-TSCA study precludes a full assessment of the data, this chemical is not manufactured or marketed and, therefore, does not pose any risk to workers or the environment.

If you have any questions regarding this submission, please contact Dr. Robert K. Hinderer at (216) 447-5181.

Sincerely,

THE B.F.GOODRICH COMPANY

Carl A. Mattia/jk

Carl A. Mattia
Vice President
Environmental, Health and
Safety Management Systems

CAM/jk

AN-1211

HILL TOP RESEARCH, INC.
Miamiville, Ohio 45147

Contains No CBI

REPORT 72-470 DATE: November 1, 1972

ACUTE TOXICITY AND IRRITATION STUDIES

FOR

The B. F. Goodrich Company

HILL TOP RESEARCH, INC.
Miamiville, Ohio 45147

IMPORTANT NOTICE

SAMPLE DISPOSAL
PROCEDURE

At the conclusion of a test program, two units of each sample used will be stored and remaining samples will be destroyed. No materials will be maintained longer than six months after the completion of the study unless the client notifies Hill Top Research, Inc.

New drugs are exempt from the above procedure. They will be retained or returned to the client.

HILL TOP RESEARCH, INC.
Miamiville, Ohio 45147

November 1, 1972

72-470-21

ACUTE TOXICITY AND IRRITATION STUDIES

For The B. F. Goodrich Company

PURPOSE

This study was conducted to evaluate the acute oral, dermal and inhalation toxicity and the acute eye irritation potential of the test materials in accordance with Section 362.116 of the Regulations for the Enforcement of the Federal Insecticide, Fungicide and Rodenticide Act, Interpretation 18 (Revised, Federal Register, April 4, 1969).

TEST MATERIALS

The samples were received from The B. F. Goodrich Company on August 10, 1972 for use in these studies. The samples were labled A.O. 3125 and 3030 x 20. Each material was a white powder.

PROCEDURE

1. Acute Oral Administration - Rats

Each test sample was administered orally by stomach tube to five groups, each composed of five male and five female albino rats (Laboratory Supply Company, weight range 183 to 222 grams for the males and 146-177 grams for the females). The sample was administered as a 10.0 or 50.0 percent weight/volume suspension in corn oil (Mazola) at dosage levels of 0.464, 1.00, 2.15, 4.64, and 10.0 gm/kg for the males and 0.100, 0.215, 0.464, 1.00 and 2.15 gm/kg for the females.

Food was withheld from the rats for 24 hours prior to dosage. Following dosage, food consisting of commercial pellets and water were available ad libitum. The rats were housed in groups in wire mesh cages suspended above the droppings. All animals were observed closely for gross signs of systemic toxicity and mortality at frequent intervals during the day of dosage, and at least once daily thereafter for a total of 14 days. Gross necropsies were performed on the animals that died. At the end of the 14-day observation period the surviving rats were weighed, sacrificed by cerebral concussion and gross necropsies were performed. Statistical analysis of the mortality data was by the moving average method.[1]

[1] C. S. Weil, Biometrics 8, 1952, p. 249

2. Acute Dermal Application - Rabbits

Each test material was applied to the skin of four groups, each composed of four albino rabbits (weight range 1892 to 3693 grams). The dose was applied to the abdominal skin area from which the fur had been previously removed with electric clippers. The abdominal skin area of two rabbits in each group was abraded by making a series of longitudinal minor epidermal incisions spaced one to two centimeters apart, using a hypodermic needle as a cutting tool. The abrasions were sufficiently deep to penetrate the epidermis but not to induce bleeding. The skin of the remaining two rabbits in each group remained intact.

Each sample was moistened with sufficient distilled water to form a paste and was applied at dosage levels of 1.00, 2.15, 4.64 and 10.0 gm/kg of body weight.

The sample was placed on a sleeve of freezer wrapping paper which was then wrappped around the trunk of the animal and secured with staples. An outer layer of gauze and tape was placed around the trunk of the animal. The rabbit was immobilized for 24 hours in a wooden restraining stock. At the end of the 24-hour exposure period the binder was removed and any unabsorbed sample remaining on the skin was removed by gentle sponging with a moistened towel. Each rabbit was examined thoroughly for gross signs of systemic toxicity and dermal irritation. The rabbits were placed in individual metal cages elevated above the droppings. Food, consisting of commercial rabbit pellets, and water were available at all times. All rabbits were maintained for 14 days following completion of the exposure period. Examinations for gross signs of systemic toxicity and dermal irritation were carried out at frequent intervals during this period.

At the end of the 14-day observation period the rabbits were weighed, sacrificed by air embolism, and a gross necropsy was performed on each animal.

3. Acute Eye Application - Rabbits

One hundred milligrams of each undiluted sample was applied to the left eye of each of each of six albino rabbits. The right eyes were untreated and served as controls. Examinations for gross signs of eye irritation were made at 24, 48 and 72 hours following application. Scoring of irritative effects was according to the method of Draize, in which corneal, iris and conjunctival effects are scored separately.[1] This method is reproduced in the addendum

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[1] J. H. Draize, "Dermal Toxicity," in Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics, The Staff of the Division of Pharmacology of the Federal Food and Drug Administration (Austin, Texas: The Editorial Committee of the Association of Food and Drug Officials of the United States, 1959), p 51.

following Tables 1 and 2. In this scoring system injuries to the cornea and iris may represent as much as 80 percent of the total score. Cornea and iris scores are heavily weighted because of the essential role of these organs in vision.

4. Acute Inhalation Exposure - Rats

Two groups of five male and five female albino rats (Laboratory Supply Company, weight range 319 to 379 grams for the males and 197 to 252 grams for the females) were used in this study. The rats were exposed to a dust of A.O. 3125 or 3030 x 20 in an inhalation chamber for one hour. The concentration of each test material in the chamber atmosphere was determined by the following formula:

$$\frac{A}{B \times C} = D$$

Where A = Weight of sample in milligrams used during the exposure period
B = Air flow (liters/minute)
C = Duration of exposure (minutes)
D = Concentration of sample in chamber atmosphere (milligrams/liter)

In this study A was 165,000 milligrams for A.O. 3125 and 70,000 milligrams for 3030 x 20, B was 15 liters per minute, C was 60 minutes and D was 183.2 milligrams per liter for A. O. 3125 and 77.8 milligrams per liter for 3030 x 20.

The chamber used in this study consisted of a glass jar, 29 cm in diameter and 30 cm deep, fitted with a plexiglass lid. The lid contained air intake and exit tubes positioned at the top and bottom of the chamber, respectively. Each sample was placed in a conical flask in which the air was directed tangentially to produce a swirling action which introduced the dust into the entering air stream and thence into the chamber.

At the conlusion of the one-hour exposure period animals were removed from the chamber and housed by groups in wire mesh cages elevated above the droppings. Commercial pellets and water were available to the animals ad libitum.

Observations were made of the appearance and behavior of the animals continuously during the exposure period and at frequent intervals thereafter for a total of 14 days. At the end of the observation period the animals were weighed, sacrificed by cerebral concussion and gross necropsies were performed.

RESULTS

1. Acute Oral Administration - Rats

A.O. 3125

No mortalities occurred in either male or female rats at the highest dosage level tested. Therefore, the acute oral LD_{50} of A.O. 3125 is greater than 10.0 gm/kg of body weight for either sex.

3030 x 20

The mortality results during the 14-day observation period for male rats are presented below. Values are number of animals dead/number of animals tested, cumulative.

Dose	Time of Death										
	Hours				Days						
gm/kg	1	2	4	24	2	3	4	5	6-8	9	10-14
0.464	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
1.00	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	2/5
2.15	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	5/5
4.64	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	5/5
10.0	0/5	0/5	0/5	0/5	4/5	5/5					

LD_{50}, gm/kg 1.08
95% Confidence Limits, gm/kg 0.741-1.57

The mortality results during the 14-day observation period for female rats are presented below. Values are number of animals dead/number of animals tested, cumulative.

Dose	Conc. of Suspension	Time of Death									
		Hours				Days					
gm/kg	% w/v	1	2	4	24	2	3	4	5	6	7-14
0.100	10	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
0.215	10	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
0.464	50	0/5	0/5	0/5	0/5	0/5	0/5	0/5	1/5	1/5	1/5
1.00	50	0/5	0/5	0/5	0/5	0/5	0/5	0/5	1/5	1/5	1/5
2.15	50	0/5	0/5	0/5	0/5	0/5	4/5	5/5			

LD_{50}, gm/kg 1.10
95% Confidence Limits, gm/kg 0.661-1.83

Gross signs of systemic toxicity noted among the male rats included depression, depressed righting and placement reflexes, ataxia, apparent hypothermia; tremors, hypersensitivity to tactile stimulus, piloerection, shallow respiration, convulsions, and serosanguineous stains around the nose.

Similar signs were observed in the female rats. In addition, dorsal alopecia was noted in a few of the females beginning during the middle of the observation period and continuing for the remainder of the study.

Average body weight gains for the surviving male rats are shown below.

Dose gm/kg	Average Body Weight Start gm	Finish gm	Gain gm
0.464	207	276	69
1.00	204	253 (3 rats)	49

The average body weight gain for the rats at the 0.464 gm/kg level was within normal limits for rats of the age, sex and strain used in this study. Slight growth suppression occurred at the 1.00 gm/kg level.

Average body weight gains for the surviving females are shown below.

Dose gm/kg	Average Body Weight Start gm	Finish gm	Gain gm
0.100	162	221	59
0.215	163	216	53
0.464	159	208 (4 rats)	49
1.00	162	198 (4 rats)	36

Average body weight gains for the three lower dosage levels were within normal limits for rats of the age, sex and strain used in this study. Apparent slight growth suppression occurred at the 1.00 gm/kg level.

Gross necropsies performed on the rats that died generally showed congestion of the lungs, kidneys and adrenals, slight to marked depletion of body fat stores, and autolytic changes. Gross necropsies performed on the rats at termination showed depletion of body fat stores in the male rats at the 0.464 and 1.00 gm/kg levels. No other significant gross pathology was noted.

2. Acute Dermal Application - Rabbits

Neither sample produced any mortalities at any dosage level tested. Therefore, the acute dermal LD_{50} for A.O. 3125 and 3030 x 20 for albino rabbits in greater than 10.0 gm/kg of body weight.

With the exception of slight to moderate emaciation noted in approximately one-half of the rabbits receiving A.O. 3125 and three-quarters of the rabbits receiving 3030 x 20 no significant signs of systemic toxicity were observed during the study.

Body weight changes for the rabbits receiving A.O. 3125 are shown below.

Rabbit No.	Sex	Dose gm/kg	Skin		Body Weight Start gm	Body Weight Finish gm	Change gm
			Intact	Abraded			
1	F	1.00	X		2405	2313	-92
2	M	1.00	X		3016	3200	184
3	F	1.00		X	2922	2586	-336
4	M	1.00		X	2736	2936	200
5	F	2.15	X		2682	2827	145
6	M	2.15	X		3364	3257	-107
7	F	2.15		X	3043	2954	-89
8	M	2.15		X	3180	2634	-546
9	F	4.64	X		3693	3633	-60
10	M	4.64	X		2106	2378	272
11	F	4.64		X	2371	2465	74
12	F	4.64		X	2097	1695	-402
13	M	10.0	X		1892	2393	501
14	F	10.0	X		2417	2559	142
15	F	10.0		X	2275	2320	45
16	F	10.0		X	2107	2274	167

Although approximately 50% of the animals lost weight this finding is apparently not dose-related.

Body weight changes for the rabbits receiving 3030 x 20 are shown below.

Rabbit No.	Sex	Dose gm/kg	Skin		Body Weight Start gm	Body Weight Finish gm	Change gm
			Intact	Abraded			
1	M	1.00	X		1924	2119	195
2	F	1.00	X		2466	2468	2
3	M	1.00		X	3160	2966	-194
4	F	1.00		X	2940	2764	-176
5	M	2.15	X		3148	3157	5
6	F	2.15	X		2758	2874	116
7	M	2.15		X	2726	2944	118
8	F	2.15		X	3455	3388	-68
9	M	4.64	X		2379	2494	115
10	M	4.64	X		2241	2334	93
11	M	4.64		X	2160	2143	-17
12	F	4.64		X	1956	2234	278
13	M	10.0	X		2170	2140	-30
14	M	10.0	X		2021	2103	82
15	M	10.0		X	3178	3161	-17
16	M	10.0		X	2178	2216	38

As shown above the majority of the animals gained weight during the study. Losses in weight were apparently not dose-related.

When the binders were removed at the end of the 24-hour exposure period the binders contained dry sample indicating dermal absorption of the water used to moisten the sample prior to application. No differences were noted between the two samples.

Local skin irritative effects were minimal and were confined to mild erythema noted in the majority of the animals on removal of the binders at the end of the exposure period. An occasional rabbit showed mild desquamation usually confined to the abrasions, during the latter portion of the study. No significant differences were noted between the samples. Gross necropsies performed at termination showed no significant gross pathology.

3. Acute Eye Application - Rabbits

The results following application of A.O. 3125 and 3030 x 20 to the eyes of albino rabbits are presented in Tables 1 and 2, respectively.

A.O. 3125 produced little or no gross signs of eye irritation in five of the rabbits. The sixth rabbit showed swelling with partial eversion of the lids at the 24-hour reading only.

3030 x 20 produced mild corneal opacity in four of the six rabbits. Moderate conjunctivitis was observed in all rabbits.

4. Acute Inhalation Toxicity - Rats

No mortalities occurred among five male and five female albino rats following a one-hour exposure to a calculated air concentration of 183.2 mg/liter of A.O. 3125 in an air inhalation chamber.

Signs observed during the exposure period included preening, masticatory movements, hyperactivity, lacrimation, gasping, and serosanguineous stains around the nose. The animals also showed a large quantity of dust (sample) on their bodies. At the conclusion of the exposure period the rats appeared slightly depressed and were wheezing. One male and one female showed depressed righting and placement reflexes. Two male rats were gasping and three female rats were hypersensitive to stimuli. The latter animals continued to show hypersensitivity on the following day. On the second post-dosage exposure day and for the remainder of the study all rats appeared grossly normal.

The average body weight gain for the male rats was 25 grams and for the female rats 9 grams.

The body weight gain for both sexes was below normal for rats of the age and strain used in this study.

Gross necropsies performed at termination showed no gross pathology.

No mortalities occurred among five male and five female albino rats following a one-hour exposure to a calculated air concentration of 77.8 mg/l of 3030 x 20 in an inhalation chamber.

Signs observed during the exposure period included preening and masticatory movements. In addition, a few exhibited serosanguineous stains around the nose. All rats showed white dust (sample) on their bodies.

At the conclusion of the exposure period a few animals showed excessive salivation and serosanguineous stains around the nose. On the following day the rats appeared depressed and showed depressed righting and placement reflexes, and serosanguineous stains around the nose. On the second post-exposure day the animals appeared slightly depressed and showed slightly swollen and pale eyes, and appeared slightly emaciated. For the next few days the rats appeared grossly normal. On the tenth post-exposure day and for the remainder of the study two female rats showed slight dorsal alopecia.

The average body weight gain for the male rats was two grams and for the female rats 13 grams. These gains were below the normal range for rats of the age and strain used in this study.

Gross necropsies performed on the rats at termination showed no gross pathology.

SUMMARY

The acute oral, dermal, and inhalation toxicity, and the acute eye irritation potential of A.O. 3125 and 3030 x 20 was evaluated using the techniques specified in Section 362.116 of the Regulations for the Enforcement of the Federal Insecticide, Fungicide, and Rodenticide Act, Interpretation 18 (Revised, Federal Register, April 4, 1969).

The acute oral LD_{50} of A.O. 3125 for male and female albino rats was found to be greater than 10.0 gm/kg of body weight.

The acute oral LD_{50} of 3030 x 20 for male albino rats was found to be 1.08 gm/kg of body weight with 95% confidence limits of 0.741 to 1.57. The acute oral LD_{50} for female albino rats was found to be 1.10 gm/kg of body weight with 95% confidence limits of 0.661 to 1.83.

The acute dermal LD_{50} for each material for albino rabbits was found to be greater than 10.0 gm/kg of body weight.

A.O. 3125 produced essentially no eye irritation.

3030 x 20 produced corneal opacity in four of six rabbits.

The acute LC_{50} of A.O. 3125 for albino rats was found to be greater than 183.2 mg/l of air.

The acute LC_{50} of 3030 x 20 for albino rats was found to be greater than 77.8 mg/l of air.

Based on these results A.O. 3125 is non-toxic by oral ingestion, dermal absorption, and inhalation, and is not an eye irritant as those terms are defined in the above-cited Regulations.

3030 x 20 is slightly toxic by oral ingestion, non-toxic by dermal absorption and inhalation, and is an eye irritant as those terms are defined in the above-cited Regulations.

HILL TOP RESEARCH, INC.

Submitted by _____
Robert L. Doyle, B.S.
Manager of Toxicology

Approved by

_____
M. J. Thomas, Ph.D.
Executive Vice President

_____
Paul A. Majors, M.S.
Vice President-Technical Director

Table 1. Eye irritation scores in albino rabbits following application of one hundred milligrams of A.O. 3125

Rabbit Number	Time Hours	Cornea		Iris	Conjunctivae			Total Score*
		Opacity	Area		Erythema	Swelling	Discharge	
1	24	0	0	0	0	0	0	0
	48	0	0	0	0	0	0	0
	72	0	0	0	0	0	0	0
2	24	0	0	0	0	0	0	0
	48	0	0	0	0	0	0	0
	72	0	0	0	0	0	0	0
3	24	0	0	0	1	0	0	2
	48	0	0	0	0	0	0	0
	72	0	0	0	0	0	0	0
4	24	0	0	0	1	0	0	2
	48	0	0	0	0	0	0	0
	72	0	0	0	0	0	0	0
5	24	0	0	0	1	2	1	8
	48	0	0	0	0	0	0	0
	72	0	0	0	0	0	0	0
6	24	0	0	0	1	0	0	2
	48	0	0	0	0	0	0	0
	72	0	0	0	0	0	0	0

*Total score is the sum of the following three sub-totals:
(a) degree of opacity x area involved x 5
(b) iris score x 5
(c) sum of scores for erythema, swelling, and discharge x 2
Total possible score = 110.

Table 2. Eye irritation scores in albino rabbits following application of one hundred milligrams of 3030 x 20

Rabbit Number	Time Hours	Cornea		Iris	Conjunctivae			Total Score*
		Opacity	Area		Erythema	Swelling	Discharge	
7	24	1	1	0	1	2	3	17
	48	1	1	0	1	0	0	7
	72	1	1	0	0	0	0	5
8	24	1	1	1	1	2	3	22
	48	1	1	0	1	0	0	7
	72	0	0	0	0	0	0	0
9	24	0	0	0	1	1	1	6
	48	0	0	0	0	0	0	0
	72	0	0	0	0	0	0	0
10	24	1	1	1	2	3	3	26
	48	1	1	0	1	1	0	9
	72	1	1	0	0	0	0	5
11	24	0	0	0	1	2	3	12
	48	0	0	0	0	0	0	0
	72	0	0	0	0	0	0	0
12	24	1	1	0	1	2	2	10
	48	1	1	0	1	1	1	11
	72	1	1	0	1	1	1	11

*Total score is the sum of the following three sub-totals:
(a) degree of opacity x area involved x 5
(b) iris score x 5
(c) sum of scores for erythema, swelling, and discharge x 2
Total possible score = 110.

FROM: J. H. Draize, "Dermal Toxicity," in Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics, The Staff of the Division of Pharmacology of the Federal Food and Drug Administration (Austin, Texas: The Editorial Committee of the Association of Food and Drug Officials of the United States, 1959).

TABLE 2

Scale for Scoring Ocular Lesions

(1) Cornea
- (A) Opacity-degree of density (area most dense taken for reading)
  - No Opacity 0
  - Scattered or diffuse area, details of iris clearly visible 1
  - Easily discernible translucent areas, details of iris slightly obscured. 2
  - Opalescent areas, no details of iris visible, size of pupil barely discernible. 3
  - Opaque, iris invisible 4
- (B) Area of cornea involved
  - One quarter (or less) but not zero 1
  - Greater than one quarter, but less than half 2
  - Greater than half, but less than three quarters 3
  - Greater than three quarters, up to whole area 4

A × B × 5 Total maximum = 80

(2) Iris
- (A) Values
  - Normal 0
  - Folds above normal, congestion, swelling, circumcorneal injection (any or all of these or combination of any thereof) iris still reacting to light (sluggish reaction is positive) 1
  - No reaction to light, hemorrhage, gross destruction (any or all of these). 2

A × 5 Total maximum = 10

(3) Conjunctivae
- (A) Redness (refers to palpebral and bulbar conjunctivae excluding cornea and iris)
  - Vessels normal 0
  - Vessels definitely injected above normal 1
  - More diffuse, deeper crimson red, individual vessels not easily discernible. 2
  - Diffuse beefy red 3
- (B) Chemosis
  - No swelling 0
  - Any swelling above normal (includes nictitating membrane) 1
  - Obvious swelling with partial eversion of lids 2
  - Swelling with lids about half closed 3
  - Swelling with lids about half closed to completely closed 4
- (C) Discharge
  - No discharge 0
  - Any amount different from normal (does not include small amounts observed in inner canthus of normal animals) 1
  - Discharge with moistening of the lids and hairs just adjacent to lids. 2
  - Discharge with moistening of the lids and hairs, and considerable area around the eye 3

Score (A + B + C) × 2 Total maximum = 20

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Carl A. Mattia
Vice President
Environmental Health and Safety Management Systems
The BFGoodrich Company
3925 Embassy Parkway
Akron, Ohio 44313-17992

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

NOV 0 4 1994

EPA acknowledges the receipt of information submitted by your organization under Section 8(e) of the Toxic Substances Control Act (TSCA). For your reference, copies of the first page(s) of your submission(s) are enclosed and display the TSCA §8(e) Document Control Number (e.g., 8EHQ-00-0000) assigned by EPA to your submission(s). Please cite the assigned 8(e) number when submitting follow-up or supplemental information and refer to the reverse side of this page for "EPA Information Requests".

All TSCA 8(e) submissions are placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA §8(e) policy statement (43 FR 11110, March 16, 1978). Confidential submissions received pursuant to the TSCA §8(e) Compliance Audit Program (CAP) should already contain information supporting confidentiality claims. This information is required and should be submitted if not done so previously. To substantiate claims, submit responses to the questions in the enclosure "Support Information for Confidentiality Claims". This same enclosure is used to support confidentiality claims for non-CAP submissions.

Please address any further correspondence with the Agency related to this TSCA 8(e) submission to:

Document Processing Center (7407)
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Washington, D.C. 20460-0001

EPA looks forward to continued cooperation with your organization in its ongoing efforts to evaluate and manage potential risks posed by chemicals to health and the environment.

Sincerely,

Terry R. O'Bryan

Terry R. O'Bryan
Risk Analysis Branch

Enclosure

12994 A

Triage of 8(e) Submissions

Date sent to triage: OCT 14 1994

NON-CAP CAP

Submission number: 12994 A

TSCA Inventory: Y N D

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO AQUATO

Group 2 - Ernie Falke (1 copy total)

ATOX SBTOX SEN w/NEUR

Group 3 - Elizabeth Margosches (1 copy each)

STOX CTOX EPI RTOX GTOX

STOX/ONCO CTOX/ONCO IMMUNO CYTO NEUR

Other (FATE, EXPO, MET. etc.): _____

Notes:

THIS IS THE ORIGINAL 8(e) SUBMISSION; PLEASE REFILE AFTER TRIAGE DATABASE ENTRY

For Contractor Use Only

entire document: 0 1 2 **pages** 1, 2 **pages** 1, 2, tab

Notes: Double-sided

Contractor reviewer : NEB **Date:** 9/7/94

CECATS\TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA:
Submission # 8EHQ-0494-12994 SEQ: A

TYPE: INT SUPP FLWP

SUBMITTER NAME: B.F. Goodrich
Company

INFORMATION REQUESTED: FLW P DATE:
0501 NO INFO REQUESTED
0502 INFO REQUESTED (TECH)
0503 INFO REQUESTED (VOL ACTIONS)
0504 INFO REQUESTED (REPORTING RATIONALE)

DISPOSITION:
0639 REFER TO CHEMICAL SCREENING
0678 CAP NOTICE

VOLUNTARY ACTIONS:
0401 NO ACTION REPORTED
0402 STUDIES PLANNED/UNDERWAY
0403 NOTIFICATION OF WORKERS/OTHERS
0404 LABEL/MSDS CHANGES
0405 PROCESS/HANDLING CHANGES
0406 APP/USE DISCONTINUED
0407 PRODUCTION DISCONTINUED
0408 CONFIDENTIAL

SUB DATE: 04/15/94 OTS DATE: 04/19/94 CSRAD DATE: 08/08/94

CHEMICAL NAME: CAS#

ure-rite 20	51976-94-4

INFORMATION TYPE:		P F C
0201	ONCO (HUMAN)	01 02 04
0202	ONCO (ANIMAL)	01 02 04
0203	CELL TRANS (IN VITRO)	01 02 04
0204	MUTA (IN VITRO)	01 02 04
0205	MUTA (IN VIVO)	01 02 04
0206	REPRO/TERATO (HUMAN)	01 02 04
0207	REPRO/TERATO (ANIMAL)	01 02 04
0208	NEURO (HUMAN)	01 02 04
0209	NEURO (ANIMAL)	01 02 04
0210	ACUTE TOX. (HUMAN)	01 02 04
0211	CHR. TOX. (HUMAN)	01 02 04
0212	ACUTE TOX. (ANIMAL)	01 02 04
0213	SUB ACUTE TOX (ANIMAL)	01 02 04
0214	SUB CHRONIC TOX (ANIMAL)	01 02 04
0215	CHRONIC TOX (ANIMAL)	01 02 04

INFORMATION TYPE:		P F C
0216	EPI/CLIN	01 02 04
0217	HUMAN EXPOS (PROD CONTAM)	01 02 04
0218	HUMAN EXPOS (ACCIDENTAL)	01 02 04
0219	HUMAN EXPOS (MONITORING)	01 02 04
0220	ECO/AQUA TOX	01 02 04
0221	ENV. OCCC/REL/FATE	01 02 04
0222	EMER INCI OF ENV CONTAM	01 02 04
0223	RESPONSE REQEST DELAY	01 02 04
0224	PROD/COMP/CHEM ID	01 02 04
0225	REPORTING RATIONALE	01 02 04
0226	CONFIDENTIAL	01 02 04
0227	ALLERG (HUMAN)	01 02 04
0228	ALLERG (ANIMAL)	01 02 04
0239	METAB/PHARMACO (ANIMAL)	01 02 04
0240	METAB/PHARMACO (HUMAN)	01 02 04

INFORMATION TYPE:		P F C
0241	IMMUNO (ANIMAL)	01 02 04
0242	IMMUNO (HUMAN)	01 02 04
0243	CHEM/PHYS PROP	01 02 04
0244	CLASTO (IN VITRO)	01 02 04
0245	CLASTO (ANIMAL)	01 02 04
0246	CLASTO (HUMAN)	01 02 04
0247	DNA DAM/REPAIR	01 02 04
0248	PROD/USE/PROC	01 02 04
0251	MSDS	01 02 04
0299	OTHER	01 02 04

TRIAGE DATA:	NON-CBI INVENTORY	ONGOING REVIEW	SPECIES	TOXICOLOGICAL CONCERN:
	YES	YES (DROP/REFER)	RAT	LOW
	NO	NO (CONTINUE)	RBT	MED
	IN TERMINI	REFER		HIGH

USE: Rubber Accelerator

PRODUCTION:

COMMENTS:

-CPSS- 1214941614

0 0 0 0 0 0 0 0 0 0 0 0

> <ID NUMBER>
8(E)-12994A-01

> <TOX CONCERN>
L

> <COMMENT>
A.O. 3125: ACUTE ORAL TOXICITY IN RATS IS LOW CONCERN. ANIMALS WERE DOSED AT LEVELS OF 0.464, 1.0, 22.15, 4.64, AND 10.0 G/KG MALE AND .0100, 0.215, 0. 464, 1.0, AND 2.15 FEMALE. THERE WAS NO MORTALITY IN EITHER SEX. ACUTE DERMAL TOXICITY IN RABBITS IS LOW CONCERN. ANIMALS WERE DOSED AT LEVELS OF 1.0, 2.15, 4.64, AND 10.0 G/KG ON INTACT OR ABRADED SKIN. THERE WERE NO MORTALITIES AMONG THE 16 ANIMALS. ONE HALF OF THE ANIMALS WERE EMACIATED. MILD ERYTHEMA WAS NOTED ON THE TEST SITE OF SOME ANIMALS. ACUTE EYE IRRITATION IN RABBITS IS LOW CONCERN. THERE WAS LITTLE OR NO SIGNS OF EYE IRRITATION IN 5/6 RABBITS. ONE RABBIT SHOWED SWELLING WITH PARTIAL EVERSION OF THE LIDS AT 24 HOURS. ACUTE INHALATION TOXICITY IN RATS IS LOW CONCERN. 10 RATS WERE EXPOSED TO 183.2 MG/L FOR ONE HOUR. THERE WERE NO MORTALTITIES. CLINICAL SIGNS INCLUDED PREENING, MASTICATORY MOVEMENTS, HYPERACTIVITY, LACRIMATION, GASPING, AND SEROSANGUINEOUS STAINS AROUND THE NOSE. AFTER EXPOSURE ANIMALS WERE HYPERSENSITIVE TO STIMULI AND A FEW HAD DEPRESSED RIGHTING AND PLACEMENT REFLEXES. BODY WEIGHT GAIN WAS BELOW NORMAL FOR BOTH SEXES.

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-CPSS- 1214941614

0 0 0 0 0 0 0 0 0 0 0
> <ID NUMBER>
8(E)-12994A-02

> <TOX CONCERN>
L

> <COMMENT>
3030 X 20:ACUTE ORAL TOXICITY IS LOW CONCERN BASED ON A MALE LD50 OF 1.08 G/KG AND A FEMALE LD50 OF 1.10 G/KG. DOSE AND MORTALITY DATA ARE AS FOLLOWS (G/KG): MALES: 0.464 (0/5), 1.0 (2/5), 2.15
(5/5), 4.64 (5/5), 10.0 (5/5); FEMALES: 0.100 (0/5), 0.215 (0/5), 0.464 (1/5), 1.0 (1/5), 2.15 (5/5). GROSS SIGNS INCLUDED DEPRESSION, DEPRESSED RIGHTING AND PLACEMENT REFLEXES, ATAXIA, APPARENT
HYPOTHERMIA, TREMORS, HYPERSENSITIVITY TO TACTILE STIMULUS, PILOERECTION, SHALLOW RESPIRATION, CONVULSIONS, AND SEROSANGUINEOUS STAINS AROUND THE NOSE. NECROPSY OF THE DECEDENTS SHOWED CONGESTION OF
THE LUNGS, KIDNEYS, AND ADRENALS, SLIGHT TO MARKED DEPLETION OF BODY FAT STORES, AND AUTOLYTIC CHANGES. ACUTE DERMAL TOXICITY IN RABBITS IS LOW CONCERN. ANIMALS WERE DOSED AT LEVELS OF 1.0, 2.15,
4.64, AND 10.0 G/KG. THERE WERE NO MORTALITIES. MOST ANIMALS HAD MILD ERYTHEMA. FEW HAD MILD DESQUAMATION USUALLY CONFINED TO ABRADED SITES. ACUTE EYE TOXICITY IN RABBITS IS LOW CONCERN. 4/6
ANIMALS SHOWED MILD CORNEAL OPACITY AND ALL SHOWED MODERATE CONJUNCTIVITIS. ACUTE INHALATION TOXICITY IN RATS IS LOW CONCERN. ANIMALS WERE EXPOSED TO 77.8 MG/LG OF THE TEST MATERIAL FOR ONE HOUR.
THERE WERE NO MORTALITIES. CLINICAL SIGNS INCLUDED PREEENING, MASTICATORY MOVEMENTS, EXCESSIVE SALIVATION, AND SEROSANGUINEOUS STAINS AROUND THE NOSE. ANIMALS ALSO WERE SLIGHTLY DEPRESSED, HAD SLIGHTLY SWOLLEN EYES AND SLIGHTLY EMACIATED POST EXPOSURE. 2 FEMALES SHOWED SLIGHT DORSAL ALOPECIA.

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